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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/653,406	09/01/2000	Jennifer L. West	RICE 100	7133

7590 07/06/2005  
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EXAMINER

FUBARA, BLESSING M

ART UNIT	PAPER NUMBER
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1618

DATE MAILED: 07/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

<b>Office Action Summary</b>	<b>Application No.</b>	<b>Applicant(s)</b>	
	09/653,406	WEST ET AL.	
	<b>Examiner</b>	<b>Art Unit</b>	
	Blessing M. Fubara	1618	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 April 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 18 and 20-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 18 and 20-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

5.0.2

### **DETAILED ACTION**

Examiner acknowledges receipt of amendment, remarks and exhibits, all filed 04/1/05.

Claims 18 and 20-24 are pending.

#### ***Claim Rejections - 35 USC § 112***

1. The rejection of claim 18 under 35 U.S.C. 112, first paragraph, because of the recitation of preventative or prophylactic agent is withdrawn in light of the amendment. However, claim 23 continues to recite "to prevent" and therefore a rejection under 35 USC 112 is made below. Also, claim 22 includes wound healing, restinosis, thrombosis, asthma, arthritis and erectile dysfunction in a Markush group and a Markush group should incorporate with a group related subject matter, drugs or conditions. In this case, the relationship of erectile dysfunction with asthma is not immediately discerned. Secondly, how is arthritis related to erectile dysfunction and asthma.
2. Claim 23 rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for treating surgical adhesions, does not reasonably provide enablement for preventing surgical adhesions. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. The stage at which to begin the preventing of the surgical adhesion is not disclosed and there is no data showing the success rate of the prevention of the adhesion. To prevent, the incidence must be kept from happening. Since there is no exemplification of how reliable the macromer is in preventing the surgical adhesion or keeping the surgical adhesion from occurring in all cases that the macromer may have been used and since the specification does not provide guidance on how to perform the preventing, the rate of

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success and the reliability of the process and since the standard of preventing is high, it would require a great deal of experimentation to proactive the invention.

3. The rejection of claim 23 rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is withdrawn in light of the amendment.

4. Claims 22 and 24 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Several conditions are recited in claim 22 as belonging to the same group by the Markush language. However, the relationship of restenosis and erectile dysfunction is not clear; the relationship of thrombosis and asthma and erectile dysfunction is not also clear. This is only a representative sample of what is not clear about the relatedness of all the conditions listed in the claim. The conditions appear not related. The other question is: how possible/probable is it for the NO carrying macromer to be effective in treating all these unrelated conditions? Applicants are respectfully requested amend the claim to reflect only related conditions in the Markush grouping since only related conditions should be grouped together in the Markush group.

5. Claim 18 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Therapeutic or diagnostic agents are selected from the group consisting of ... and diagnostic agents in claim 18. How is a diagnostic agent selected from diagnostic agent? A

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diagnostic agent can be inorganic molecule, biologically active molecule, protein or carbohydrate or organic molecule.

6. The specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification and in the claims.

### ***Double Patenting***

7. Claims 20-24 remain provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 20-25 of copending Application No. 10/129418. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn method of treatment comprising administering macromer composition comprising nitric oxide (NO).

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicants indicate in the remarks of 09/02/04 that any double patenting issues will be addressed when allowable subject is found. The rejection is thus made again since the co-pending application is still pending and since no terminal disclaimer is provided. However, applicants in the remarks now filed on 04/11/05 point to the earlier filing status of the examined application and again state that any double patenting issues will be resolved upon indication of allowable subject matter. The rejection is not held in abeyance and will continue to be made until the resolution of the double patenting issues.

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*“Stint” continues to be in claim 24. Applicants are respectfully requested to comment on the “stint.” If applicants intent to recite “stint,” applicants are respectfully requested to point out how the “stint” is deployed.*

The instant claims are directed to method for controlled release of therapeutic or diagnostic agents and the method comprises administering to a tissue in need thereof, a biocompatible, polymerizable macromer composition that comprises at least one nitric oxide (NO) carrying region...and wherein the NO or the NO modulating compound is released from the macromer composition following in situ polymerization.... Based on the method where the composition polymerizes in situ to release the NO or the NO modulating compound, the following art of interest is noted.

Smith et al. (WO 96/32136, cited on PTO Form 1449) discloses that a polymer bound nitric oxide/nucleophile adduct composition can be applied with specificity to a biological site of interest and the site specific application of the polymer bound adduct composition enhances the selectivity of the action of the nitric oxide releasing  $N_2O_2^-$  functional group (page 7, lines 19-35). The nitric oxide is bound to the polymer physically or chemically (page 6, lines 22-30). The composition of Smith is not a prepolymer that would polymerize in situ to release NO under physiological conditions.

Diodati et al. (“Complexes of Nitric Oxide with Nucleophiles as Agents for the Controlled Biological Release of Nitric Oxide: Hemodynamic Effect in the Rabbit,” in Journal of Cardiovascular Pharmacology, 22:287-292, cited on PTO Form 1449) discloses the hemodynamic effect of Nitric Oxide/Nucleophile complexes. These complexes do not polymerize in situ to release NO.

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Saavedra et al. (US 5,632,981) discloses nitric oxide/nucleophile complexes that are capable of releasing nitric oxide under physiological conditions and the complex comprises peptide, polypeptide, protein or nucleic acid, to which is bound nitric acid releasing compound (abstract; column 3, lines 55-60; column 5, lines 55-60; column 6, lines 45-49). The complex of Saavedra does not polymerize in situ to release nitric oxide.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is (571) 272-0594. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on (571) 272-0602. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Blessing Fubara  
Patent Examiner  
Tech. Center 1600

